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| EXAMINER |
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MAHAFKEY, KELLY J

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1794

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/502,108 | <b>Applicant(s)</b><br>KWELDAM, ADRIAAN CORNELIS |  |
|                              | <b>Examiner</b><br>Kelly Mahafkey    | <b>Art Unit</b><br>1794                          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-14 and 21-27 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/21/04</u> . | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-14, and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "Method for the preparation of a meat substitute product which comprises protein, wherein: ...b) the composition from step a) is *formed into a homogenous mixture*, c) the mixture from step b) is mixed with a solution of a metal cation with a valency of at least 2 in order *to form a fibrous product*... wherein the protein material comprises a milk protein material, and the mixture of a milk protein material, hydrocolloid which precipitates with metal cations and water *is formed in the presence of an amount of a calcium complex forming agent*." It is unclear as to in which step, i.e. the forming step recites in b or the forming step recited in c, the calcium complex forming agent is present.

Claim 6 recites, "Method according to claim 4, wherein the phosphate material is as sodium polyphosphate (NaPO<sub>3</sub>)<sub>n</sub> wherein n ~ 25". It is unclear as to what the symbol "~" means; It is unclear if "~" symbolizes equal to, less than, greater than, or if it has some other meaning.

Claim 14 recites the limitation "wherein a finishing material selected from flavoring, colouring... ". It is unclear if applicant intends to recite a Markush group and if so the proper language is "selected from the group consisting of".

Claim 21 recites, "Method according to claim 1, wherein the fibrous product, after it has been formed and isolated is pasteurized in order to be finished". The phrase "in order to be finished is unclear" as the product of claim 1 does not appear to be an intermediate product.

Claim 24 recites, "Savory or sweet snack obtained by processing a fibrous product formed with the aid of the method according to claim 1." It is unclear as to what the phrase "product formed with the aid of the method" entails; It is unclear as to if the method according to claim 1 is utilized in full or if the teachings of the method are encompassed in some other way.

Claim 26 recites, "wherein the milk protein material is selected from cured from cheesemaking, cheese...." It is unclear if the protein material is one material selected from the group cited or if the protein material includes all the material cited. It is unclear if applicant intends to recite a Markush group and if so the proper language is "selected from the group consisting of".

Claim 27 recites, "wherein the phosphate material is selected from disodium hydrogen phosphate, sodium hexametaphosphate...." It is unclear if the phosphate material is one material selected from the group cited or if the phosphate material includes all the material cited. It is unclear if applicant intends to recite a Markush group and if so the proper language is "selected from the group consisting of".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 9, 10, 14, 23, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tetsuo et al (US 3627536).

Tetsuo teaches a method for the preparation of a meat substitute product which comprises protein, wherein: milk casein (i.e. a milk protein material), about 3% sodium alginate (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a

valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Column 2 lines 1-12, and Example 1. Tetsuo teaches that phosphoric acid, (i.e. a calcium complex forming agent) is added to reduce the pH and form the fibrous product (Column 2 lines 13-18). Tetsuo teaches that flavoring is added to the homogenous mixture (Example 2).

Claims 1, 4, 5, 8, 9, 14, and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Monsanto et al (WO 96/13177).

Monsanto teaches a method for the preparation of a meat substitute product which comprises protein, wherein: powered milk, which includes milk proteins and animal fat, about 0.1-1% gellan gum (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Page 5 lines 3-5 and 27-29, and Page 6 lines 10-21. Monsanto teaches that a phosphate, including sodium hexametaphosphate, (i.e. a calcium complex forming agent) is added to form the fibrous product (Page 5 lines 29-34).

Claims 1, 4, 5, 7, 9-12, 14, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shenouda (US 4423083).

Shenouda teaches a method for the preparation of a meat substitute product which comprises protein, wherein: whey protein or whole milk, which includes milk proteins and is a protein and water mixture, about 0.25-3% sodium alginate (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Column 1 lines 9-13, Column 2 lines 50-68, Column 3 lines 15-28, and Column 7 lines

1-20. Shenouda teaches that calcium complex forming agent is at least sufficient to form a complex with free calcium ions present (Column 7 lines 25-36 and Column 8 lines 15-37). Shenouda teaches that a phosphate, including sodium tripolyphosphate (i.e. a calcium complex forming agent) is added to form the final fibrous product (Column 8 lines 15-55). Shenouda teaches that flavoring and fats can be added to the composition (Column 3 lines 1-14). Shenouda teaches that the pH of the composition is about 7 (Example 8).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2, 6, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shenouda (US 4423083).

Shenouda teaches a method for the preparation of a meat substitute product as discussed above. Shenouda, however is silent to the method as adding a calcium complex forming agent, i.e. phosphate, to the protein and water mixture, prior to adding the hydrocolloid which precipitates with metal cations, i.e. alginate, as recited in claim 2, to the number of sodium polyphosphate units as recited in claim 6, and to the phosphate material as trisodium phosphate as recited in claim 27.

Regarding the method as adding a calcium complex forming agent, i.e. phosphate, to the protein and water mixture, prior to adding the hydrocolloid which precipitates with metal cations, i.e. alginate, as recited in claim 2, it would have been obvious to switch the order of performing process steps, i.e. the order of the addition of the ingredients into the final mixture such as adding phosphate to the protein mixture prior to adding alginate, would be obvious absent any clear and convincing evidence and/or arguments to the contrary (MPEP 2144.04 [R-1]). "Selection of any order of

performing process steps is prima facie obvious in the absence of new or unexpected results".

With regard to claim 6, it is unclear what the symbol means. The claim is being interpreted as  $n$  equal to 25. Regarding the number of sodium polyphosphate units, Shenouda teaches of adding sodium phosphate as a sequesterant to the mixture (Column 8 lines 38-55). Those of ordinary skill in the art at the time the invention was made would be able to determine the appropriate sequesterant and number of units of that sequesterant needed for the particular mixture employed. This would have been a result-effective variable that is within the determination of one skilled in the art through routine experimentation. To do so would be within the ordinary ingenuity of one of ordinary skill in the art at the time the invention was made and would not impart a patentable distinction to the claims.

Regarding the phosphate material as trisodium phosphate, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one functional equivalent, i.e. calcium complex forming phosphate, such as sodium tripolyphosphate, for another functional equivalent, such as trisodium phosphate depending on which calcium complex forming phosphate was more available at the time the invention was made. To substitute one functional equivalent for another would not make a patentable distinction to the claims absent any clear and convincing arguments and/or evidence to the contrary.

Claims 1, 4, 5, 11-13 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visser et al, (US 4118520) in view of Shenouda (US 4423083).

Visser teaches a method for the preparation of a meat substitute product which comprises protein, wherein: any protein, alkali metal phosphates (i.e. a calcium complex forming agent), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium caseinate (i.e. a solution of metal cation) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Column 1 lines 26-43, Column 2 lines 1-24, and Column 4

lines 5-26. Visser teaches that the pH is between 5 and 6.6 (Column 4 lines 5-26). Visser, however is silent to the addition of a hydrocolloid which precipitates with metal cations as recited in claim 1 and to the protein material as a dairy protein as recited in claim 1.

Shenouda teaches a method for the preparation of a meat substitute product which comprises protein, wherein: whole milk, which includes milk proteins and is a protein and water mixture, about 0.25-3% sodium alginate (i.e. a hydrocolloid which precipitates with metal cations), and water are combined, wherein the composition is formed into a homogenous mixture, the homogenous mixture is mixed with calcium chloride (i.e. a solution of metal cation with a valency of at least 2) to form a fibrous product, and the fibrous product is isolated. Refer specifically to Abstract, Column 1 lines 9-13, Column 2 lines 50-68, Column 3 lines 15-28, and Column 7 lines 1-20. Shenouda teaches that the sodium alginate is essential in forming the complex into an irreversible gum, wherein the alginate is a thickener (Column 2 lines 27-31 and Column 3 lines 21-28).

Regarding the addition of a hydrocolloid which precipitates with metal cations, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include sodium alginate as taught by Shenouda in the meat substitute product disclosed in Visser. One would have been motivated to do so in order to form a thickener meat product with a thermally irreversible gel.

Regarding the protein material as a dairy protein, Visser teaches that any suitable protein may be utilized in the meat substitute product. Shenouda teaches that dairy milk is a suitable protein for a meat substitute product. Dairy milk is known to enhance the nutritional benefits of a composition as it contains vitamins and minerals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dairy milk as the protein source of the meat substitute product in order to nutritionally enhance the meat substitute product.



Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tetsuo et al (US 3627536) in view of Lusas et al. (US 5300312).

Tetsuo teaches a method for the preparation of a meat substitute product as discussed above. Tetsuo, however is silent to the meat substitute product as pasteurized as recited in claim 21 or as packaged as recited in claim 22.

Lusas teaches of a meat substitute product which may contain animal proteins (Abstract and Column 4 lines 40-45). Lusas teaches that the product is pasteurized in order to minimize the extent of future microbial proliferation and spoilage (Column 4 lines 62-68). Lusas teaches that the product may be packaged so that it may be sold in vending machines and at news stands (Column 7 lines 1-8).

Regarding the meat substitute product as pasteurized, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pasteurize the meat substitute product as taught by Lusas in order to prevent future microbial proliferation and spoilage.

Regarding the meat substitute product as packaged, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package the substitute meat product as taught by Lusas so that it could be conveniently sold in locations such as in vending machines and on news stands.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monsanto et al (WO 96/13177) in view of Lusas et al. (US 5300312).

Monsanto teaches a method for the preparation of a meat substitute product as discussed above. Monsanto, however is silent to the meat substitute product as pasteurized as recited in claim 21 or as packaged as recited in claim 22.

Lusas teaches of a meat substitute product which may contain animal proteins (Abstract and Column 4 lines 40-45). Lusas teaches that the product is pasteurized in order to minimize the extent of future microbial proliferation and spoilage (Column 4 lines 62-68). Lusas teaches that the product may be packaged so that it may be sold in vending machines and at news stands (Column 7 lines 1-8).

Regarding the meat substitute product as pasteurized, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pasteurize the meat substitute product as taught by Lusas in order to prevent future microbial proliferation and spoilage.

Regarding the meat substitute product as packaged, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package the substitute meat product, as taught by Lusas, so that it could be conveniently sold in locations such as in vending machines and on news stands.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY MAHAFKEY whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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